

Applicant : Silviu Itescu  
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**Remarks**

Claims 1-10, 14, 16-20, 24, 35-37 and 43-50 are pending. Applicant has hereinabove cancelled claims 17 and 18 without disclaimer or prejudice to applicant's right to pursue the subject matter of these claims in the future. In addition, applicant has hereinabove amended claims 35 and 45 for clarity and has added new claims 51 and 52. Support for new claim 51 can be found in the specification as originally filed at, inter alia, page 51, line 11; page 30, line 3; page 22, lines 26 to 29; page 24, lines 23-26; page 3, lines 7-10; page 29, lines 13-14; and page 33, lines 5-10. Support for new claim 52 can be found in the specification as originally filed at, inter alia, page 7, lines 1-4; and page 14, lines 14-17. Applicant maintains that the amendments to the claims and new claims 51 and 52 raise no issue of new matter, and request entry of this Amendment.

**Restriction Requirement Under 35 U.S.C. §121**

The March 27, 2007 Office Action imposes a restriction requirement under 35 U.S.C. §121 with respect to claims 35-37 and 43-50 among the following three (3) allegedly independent and distinct inventions:

- I. Claims 35-37, 43-46, 49 and 50, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of a tissue comprising administering to the subject an amount of a human stromal-derived factor 1 $\alpha$  which induces activation of CXCR4. The Examiner stated that the election of this group requires the further election of a disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia, ischemic disease,

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diabetic heart disease or cardiomyopathy, AND the further species election of a single mode of administration selected from the group consisting of intramyocardially, via a stent, via a scaffold of via slow release formula;

- II. Claims 35-37, 43-45, 47, 49 and 50, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of a tissue comprising administering to the subject an amount of a human stromal-derived factor 1 $\beta$  which induces activation of CXCR4. The Examiner stated that the election of this group requires the further election of a disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia, ischemic disease, diabetic heart disease or cardiomyopathy, AND the further species election of a single mode of administration selected from the group consisting of intramyocardially, via a stent, via a scaffold of via slow release formula; and
- III. Claims 35-37, 43-45 and 48-50, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of a tissue comprising administering to the subject an amount of a human stromal-derived factor 1 $\gamma$  which induces activation of CXCR4. The Examiner stated that the election of this group requires the further election of a disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia, ischemic disease, diabetic heart disease or cardiomyopathy, AND the further species election of a single mode of administration selected from the group consisting of intramyocardially, via a stent, via a scaffold of via slow release formula;

#### Applicant's Response

In response to this restriction requirement, applicant hereby elects, with traverse, to prosecute the invention of Examiner's claim group II, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue which comprises administering to the subject an amount of a human stromal-derived factor 1 $\beta$  which induces activation of

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CXCR4. In addition, in response to the Examiner's species requirement, applicant hereby elects, with traverse, the species intramyocardially via a stent for prosecution at this time, consistent with applicant's previous election of the species intramyocardially in applicant's response filed January 8, 2007. In response to the requirement of election of a species of disorder, applicant hereby elects, with traverse, the species myocardial infarction for prosecution at this time.

Applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

#### Burden on the Examiner

The Examiner asserted that, inter alia, the inventions of groups I-III are directed to related processes. The Examiner also asserted that in the instant case the inventions as claimed each have different designs and effects since each group uses a unique compound. The Examiner stated that inventions as claimed are mutually exclusive since each method involves a unique agent (human stromal-derived factor 1 $\alpha$ , 1 $\beta$  or 1 $\gamma$ ) and therefore also have at least unique designs. The Examiner also asserted that the inventions as claimed do not encompass overlapping subject matter and that there is nothing of record to show them to be obvious variants. The Examiner indicated that, thus, there would be a serious burden on the Examiner if restriction is not required because the inventions require a different field of search.

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In response, applicant maintains that the statement that "there would be a serious burden on the Examiner if restriction is not required because the inventions require a different field of search" is not consistent with the fact that the search for each of groups I-III would be performed in the same class (514) and subclass (1). In addition, applicants note that searching for "stromal-derived factor-1" would presumably return art for each of the three groups.

Applicant thus maintains that there would not be a serious burden on the Examiner if restriction were not required. Since there is no serious burden on the Examiner to examine Groups I-III in the subject application, the Examiner must examine the entire application on the merits.

#### Independent and Distinct

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect...".

Applicant notes that the claims of Group I-III are related in that they are drawn to methods of use of human stromal-derived factor for treating or preventing a disorder of a tissue involving loss of cells.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

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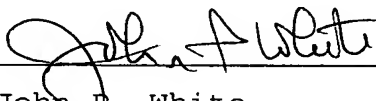
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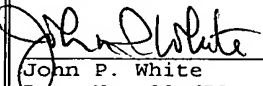
In light of the arguments presented hereinabove, applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine the pending claims on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$60.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

  
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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
 John P. White Reg. No. 28,678	5/29/07 Date